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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,679	PERA, MARTIN FREDERICK	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-56 and 68-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *50-56, 68-79* is/are allowed.

6)☒ Claim(s) *80-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed June 20, 2001 claims benefit to foreign applications PR1327, filed November 8, 2000, and PQ8242, filed June 20, 2000, both in Australia.

Applicants' amendment filed October 17, 2005, has been received and entered. \ Claims 1-49, 57-67 have been canceled. Claims 50-56 and 68-83 are pending.

Election/Restriction

Applicant's election with traverse of group I, and the election of species of noggin in Paper No. 11 was acknowledged. The requirement was deemed proper and made FINAL. In the last office action it was noted that the election of species is withdrawn.

Claims 50-56 and 68-73 are pending and currently under examination as they are drawn to methods of culturing ES cells with a BMP antagonist.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims previously objected to under 37 CFR 1.75 as being a substantial duplicate of claims 50-56 is withdrawn

The cancellation of claims have addressed the basis of the rejection.

Claim Rejections - 35 USC ➢ 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 80-83 stand rejected under 35 U.S.C. 102(b) as being anticipated by Thomson (US Patent 5,843,780) or Carpenter *et al.* (Pub. No. US2002/0019046 A1).

Applicants summarize the basis of the rejection (page 7) and argue that the teachings of Thomson and Carpenter *et al.* fail to anticipate the claims because it does not recite the limitations set forth in the method claim, in particular claim 69 (page 8). Further, it is argued that the cell being claimed is an intermediate to an ES cell and neural progenitor cell, as evidenced by the present specification (page 8). See Applicant's amendment, pages 7-8. Applicant's arguments have been fully considered, but not found persuasive.

As noted before, the claim is being given its broadest most reasonable interpretation in light of the teachings of the specification and the art of record. The term "progenitor cell" as recognized in the art is a general term which is consistent with that set forth in the specification as cited above, and for the purposes of art rejections is being interpreted by the functional ability of the cell to give rise to any somatic cell lineage. In this case, because embryonic stem cells are capable of giving rise to any somatic cell lineage, an ES cell can be interpreted to be a type of progenitor cell. The specification does not specifically define a progenitor cell however within the context of the methods the term is described as a cell which is capable of differentiation into any somatic lineage (page 14, lines 24-26). As noted previously given the guidance of the specification used to interpret the metes and bounds of the claims, they can reasonably be interpreted to broadly encompass any progenitor cell made by any method. Clearly Thomson and Carpenter *et al.* teach progenitor cells that anticipate the instant claims.

It is important to note that the present specification acknowledges that even the specific cell type produced in the working example has not fully characterized. Given the limited disclosure of the cells produced by the claimed methods and the breadth of the types of cells encompassed by the terms as recognized in the art. More specifically, with respect to claims 80 and 82, while the methods steps are given weight to what the resulting cell may or may not have no specific characteristic of the resulting cell is set forth in the product claims and further, there is no guidance nor support in the specification for which cell marker would define this change from stem cell to progenitor cell. Further, it is noted that in the methods and reduction to practice where Thomson and Carpenter *et al.* allow the cells to differentiate, they provide an intermediate population of cell which are not ES nor neuronal stem cells. With respect to claims

81 and 83, the evidence of record indicates that ES cells do not have any of these specific markers recited in the claims, and ES cells themselves would anticipate these claims. Again, Thomson teach primate embryonic stem cells. The stem cells are pluripotent capable of giving rise to the various somatic cell lineages which is demonstrated by injecting the cells into a SCID mouse and analyzing the resulting cell types (column 11, lines 12-58). With respect to the specific antibody markers, it is noted that Thomson does not specifically analyze for the presence or absence of these cell surface markers, however as recognized in the art and indicated in the present specification they represent markers on ES cell cultures which are allowed to spontaneously differentiate and are present at early time points of 7-10 days in culture (page 13, lines 20-30). Because the primate ES cells described by Thomson are highly pluripotent and not subject to differentiating conditions in culture, they would not have any of these cell surface markers. Similarly, Carpenter *et al.* teach primate pluripotent stem cells, and specifically teach that embryonic stem cells as taught by Thomson (page 4, paragraphs 45-48, in particular paragraph 46). Thus, to the extent that the instantly claimed products encompass pluripotential embryonic stem cells, Carpenter *et al.* anticipate the claims.

Again because the resulting cells are not fully describe in the present specification, and claimed as a product by process where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best,*

Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown,* 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). With respect to the methods wherein the ES cells are cultured in the presence of noggin or where noggin is used to produce a progenitor cell, any particular affect of these methods on the ES or resulting progenitor cell to differentiate from that known in the art is not set forth. Therefore in this case, the undifferentiated ES cells and progenitor cells being claimed are being interpreted to be cells defined by their functional properties which are cells capable of giving rise to any cell type of any lineage. As noted above, Thomson teach that the primate embyronic stem cells are pluripotent and capable of giving rise to the various somatic cell lineages which was demonstrated by injecting the ES cells into a SCID mouse and analyzing the resulting cell types (column 11, lines 12-58). Since the ES cells described by Thomson have the phenotypic characteristics of ES/progenitor cells recognized in the art as defined and supported by the instant specification, the primate ES cells described by Thomson anticipate the instantly claimed ES/progenitor cells which were cultured in the presence of noggin.

Conclusion

Claims 50-56, 69-79 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

As stated previously, the present disclosure is the first to propose the use of antagonists of the BMP pathway, and reduce to practice methods that demonstrate that the use of such agonists result in possibly a more directed lineage differentiation of an embryonic stem cell. Methods setting forth the generation of neural stem cells are clearly enabled as evidenced by the working examples, and the methods encompassing a less differentiated progenitor cell are considered enabled because of evidence of record, and the requirement that the differentiation pathway would require the production of intermediate cell types during the process of practicing the methods as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Levesque et al. US Patent 6,949,380 B1 (issued Sept 27, 2005) provides further evidence that BMP agonists were known in the art and could be used with different cell types to differentiate cells, in particular into neuronal cell lineages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach